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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,735	07/26/2001	Laure Dumoutier	LUD 5734 (10105486)	7869

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EXAMINER	
LEE, BETTY L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,735	DUMOUTIER ET AL.	
	Examiner	Art Unit	
	Betty Lee, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4-25* is/are withdrawn from consideration.

5)☒ Claim(s) *3* is/are allowed.

6)☒ Claim(s) *1,2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.000

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 states that the 'said molecules are mammalian molecules'. However, the specification does not indicate that the applicants have isolated the IL-20 receptor β and IL-22 receptor molecules from a representative number of mammals. The claim as written, encompasses a wide variety of mammalian molecules. The instant disclosure of a human receptor complex does not adequately describe the scope of the claimed genus of mammalian molecules.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the human receptor complex, the skilled artisan cannot envision the detailed structure of the encompassed 'mammalian IL-20 receptor β and IL-22 receptor molecules', and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The actual mammalian receptor complexes are required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only IL-20 receptor β and IL-22 receptor complex of human origin, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for human receptor molecules, does not reasonably provide enablement for all mammalian receptor molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is an IL-22R and IL-20R β complex molecule cloned and isolated from human cDNA as described in the specification. The specification does not describe the isolation of ALL mammalian IL-22R and IL-20R β complexes as stated in claim 2. The working examples described *in vitro* experiments with human receptor complexes in human cell lines, e.g. HT-29 (Human colonic adenocarcinoma) Hep G2 (human hepatocellular carcinoma), HEK-293 (human embryonic kidney). One of skill in the art would not expect to predict that the human IL-22R and IL-20R β molecules would be similar to those of other species.

Gibbs & Pennica, *Gene* 186:97-101,1997 isolated and compared human and mouse CRF2-4 (IL-10R2) genes and proteins. The reference teaches that mouse protein sequence is only '69% identical with the 325-residue hCRF2-4 protein' (Fig 2B, p 99). In addition, Tachiiri, *et al*, *Genes and Immunity*, 4:153-159, 2003 teaches that mouse and human IL-22R has '77.7% homology at the nucleotide level and 71.9% homology at the amino acid level' (Fig 1b, p154). Given this, it is not predictable how

similar other IL-22R will be to the sole disclosed species (human). The specification provides no guidance or examples as to how to isolate IL-22R from other species, including probes to be used, etc. Accordingly, it would require undue experimentation to determine how to obtain, and then obtain, a number of species commensurate in scope with the claims.

The specification provides no guidance and no working examples of isolated IL-22R and IL-20R β complex molecules from other mammalian species. Based on the prior art for mouse and human IL-22R and IL-20R β DNA and proteins, the breadth of the claims and the great amount of experimentation required to isolate receptor molecules from commensurate number of mammalian species, the claims are not enabled for the isolated IL-22R and IL-20R β molecules from the broad genus 'mammalian molecules'.

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Xie, *et al* J. Biol. Chem. 275:31335-31339, 2000 teaches that IL-22 signals through a two component receptor complex comprising of CRF2-4 and IL-22R (p31338, Fig 4b) CRF2-4 is also called IL-10R2 and IL-22R is also known as CRF2-9 or IL-22R1. The reference does not teach the IL-20Rβ subunit as part of the complex. Claim 1 has a subunit IL-22R that is in common with the subunit of the receptor complex cited in the reference. In addition, Kotenko, *et al*, J. Biol Chem. 276:2725-2732, 2001 teaches the identification of IL-10R2(CRF2-4) and IL-22R1(CRF2-9) subunits comprises the IL-22 receptor complex, thereby collaborating the findings of Xie, *et al*. The IL-20Rβ (DIRS1) subunit and IL-20Rα (CRF2-8) subunit are isolated by

Blumberg, *et al* in 2001 (Cell, 104:9-19, 2001). Both subunits form an IL-20 receptor complex. Blumberg, *et al* teaches the expression of IL-20Rα and IL-20Rβ in a variety of human tissues with skin having the highest expression of both subunits. Patients with psoriasis showed the highest expression of the IL-20 receptor complex.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Lee, Ph.D. whose telephone number is (571) 272-8152. The examiner can normally be reached on M-F 9 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLL

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER